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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Dale Brown

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BANNER & WITCOFF, LTD.
28 STATE STREET
SUITE 1800
BOSTON, MA 02109-1701

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/005,902	Applicant(s) BROWN ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/26/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments and Arguments

1. The response filed on **4/14/2010** has been entered.
2. Applicant's arguments filed 4/14/2010 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 40-50 are newly added and are pending in this office action. Claims 26-39 are cancelled.
5. The information disclosure statement (IDS) submitted on 2/26/10 is acknowledged and has been reviewed.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

No where in the specification is it contemplated “wherein each individual bristle of the toothbrush comprises longitudinal rib...” as recited in claim 40, a and b.

No proper antecedent basis or conception in context with that described in the specification at the time of filing the instant application is apparent for the recitation of “wherein each individual bristle of the toothbrush comprises longitudinal rib...” thereby constituting new matter. Applicant is invited to indicate by page and line number where such a limitation is described.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-50 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Keller (US 5,129,824) in view of Hill (US 5,993,784) and Aberg et al. (US 5,807,541) for the reasons made of record in Paper No. 20100115 and as follows.

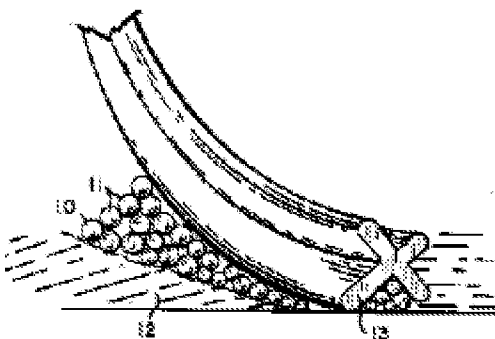
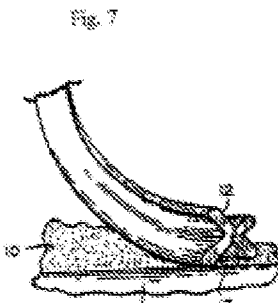
Applicant argues that (i) Keller does not teach the three steps of the claimed method. (2) Keller does not teach a toothbrush wherein each bristle of the toothbrush comprises longitudinal ribs and grooves. Instead, Keller teaches a brush with hollow bristles for the delivery of the tetracycline solution. (3) Keller does not teach a proxy brush wherein each bristle of the brush comprises ribs and grooves. Keller teaches absolutely nothing about proxy brushes - a specialized brush form which is very different from a traditional toothbrush. (4) Keller does not teach toothpaste containing an emulsion of nonionic surfactants and polydimethylsiloxanes and soft abrasives. (5) Keller does not teach a proxy gel containing an emulsion of nonionic surfactants and polydimethylsiloxanes and soft abrasives. (6) Keller does not teach a dental floss or a dental tape containing an emulsion of nonionic surfactants and polydimethylsiloxanes and releasable soft abrasives.

Applicant also argues that the Examiner's contention is that "all" toothbrushes comprise of ribs and grooves" and that typical toothbrush bristle are solid columns.

Applicant also argues that the Examiner is mistaken to say that the bristle includes 3-5 ribs and grooves.

In response the claims are drawn to a self treatment method of treating gingival detachment of at least 3 mm by removing the biofilm from the supragingival with a toothbrush wherein each individual bristle of the tooth brush comprises longitudinal ribs.

Keller specifically teaches a self-treatment method of treating gingival by brushing which one of ordinary skill in the art would expect the use of a toothbrush. While Keller is silent that the tooth brush is of individual bristles with longitudinal ribs, Hill does teach the same tooth brush having individual ribs as illustrated for comparison here:

Hill's tooth brush	Applicant's tooth brush
	

Accordingly even if Keller fails to teach the specific toothbrush, one of ordinary skill in the art would have been motivated to expand Keller's self treatment by

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incorporating Hill's teaching of using a bristle toothbrush that has longitudinal ribs as illustrated in the diagram above. Again Applicant should note that this is a rejection under 35 USC 103, and not under 35 USC 102.

Clearly a prima facie case of has been made of record why one of ordinary skill in the art would expand the teachings of Keller to include Hill's teaching of low foaming toothpaste with soft abrasives that is employed with a ribbed and grooved bristled toothbrush (as required by instant claim 40a), wherein the toothbrush includes 3-5 ribs and grooves (as it relates to claims 41-42; see abstract) and Aberg's teaching of adding other medicaments such as NSAIDs for treating periodontal disease. Therefore it is not clear what Applicant is actually arguing. Careful consideration has been given to Applicant's argument but found not persuasive for the reasons given above and already made of record. The rejection is re-iterated below to include the newly cited limitations which is also taught by Hill.

In summary:

Keller teaches a self-treatment method of treating gingival comprising: physically removing biofilm from the tooth surface (i.e., supra gingival) with a tooth brush (see abstract, as required by item 40a, which reasonably include toothpaste with soft abrasives), which also reasonably removes biofilm from the interproximal tooth surface (between the teeth) (as required by item 40b, see abstract and col. 3, lines 4-5 and 9-10). Intrinsically a toothbrush includes three to five ribs and grooves (as required by instant claims 41-42). Keller further teaches that brushing may also include the use of

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interdental tooth brush (i.e., proxy brush, see col. 3, lines 14-15), in which intrinsically the proxy brush will include three to five ribs and grooves (as required by instant claims 43-44). Keller also teaches that dental floss is employed to remove biofilm from subgingival surfaces (as required by item 40c) wherein the gingival detachment is about 3mm (see col. 7, lines 45-47). Keller further teaches the use of dental floss for applying medicament to the infected site (see col. 5, lines 1-14) which intrinsically will remove biofilm from the tooth surface because Keller teaches “the teeth are flossed in the usual manner” or “brushed” and thus will remove biofilm/plaque/food particles on the tooth. It should be noted that all tooth brushes comprise ribs and grooves (as required by instant claim 40a)

Additionally Keller teaches the use of gel (i.e., proxy gel/tooth paste intrinsically comprises soft abrasives; as required by instant claim 46; see abstract and col. 3, lines 23-25) wherein reasonably the gel contains soft abrasives for brushing the teeth. Keller also teaches that the self treatment may be carried/applied every 8-12 hours (i.e., at least once every 24 hours; as it relates to claims 48-49). Thus if applied every 8 waking hours will equate to twice every twenty four hours (see col. 7, lines 27-30, as it relates to claim 49).

Although Keller teaches other medicaments may be employed (see abstract and col. 7, lines 10-12), Keller however is silent to whether the toothpaste comprises non-ionic surfactants and polydimethylsiloxanes and also fails to teach the use of therapeutic agents such as NSAIDs (i.e., as it relates to claims 45-47) and is silent as to the method steps carried out after eating as required by instant claim 50) and also fails

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to teach wherein each individual bristle of the toothbrush comprises longitudinal ribs and grooves.

Hill and Aberg are added to remedy the deficiencies in Keller.

Hill teaches low foaming toothpaste with soft abrasives that is employed with a ribbed and grooved bristled tooth brush (wherein each individual bristle of the toothbrush comprises longitudinal ribs and grooves as required by instant claim 40a, note that the same toothbrush described by applicant is the same taught by Hill), wherein the toothbrush includes 3-5 ribs and grooves (as it relates to claims 41-42; see abstract, Figs 1-4b and col. 6, lines 47 and 58 for the abrasives) and wherein the toothpaste comprises non-ionic surfactants and polydimethylsiloxanes, (see col. 7, lines 45-47 and col. 11, line 33, as required by instant claim 40 a,b and c). Because toothpaste would necessarily be used on a toothbrush, it would be obvious that brushing of the supragingival also occurs.

However, Hill fails to teach use of specific therapeutic agents such as NSAIDs and dental floss.

Aberg et al teach reducing dental caries/cavities by administering toothpaste with a medicament such as NSAIDs for treating periodontal disease, (see abstract and col. 6, lines 49-58; as required by instant claims 45-46).

However Aberg fails to teach using ribbed and grooved bristled tooth brushes.

One of ordinary skill in the art would have been motivated to expand the teaching of Keller to remove biofilm removal with a tooth brush, proxy brush and floss by substituting the tooth brush of Keller with Hill's, since Hill specifically teach use of ribbed

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grooved bristle tooth brushes (i.e., each individual bristle of the toothbrush comprises longitudinal ribs and grooves) to brush the supragingival tooth surface of the tooth, wherein it is well known that brushing with toothpaste removes biofilm. Employing the toothbrush and the soft abrasive toothpaste of Hill will intrinsically result in the abrasives physically being worked into the supra and subgingival pockets of the patients mouth suffering from periodontal disease. It is well known in the art that brushing and flossing are used everyday for the removal of plaque/biofilm and or food particles on the teeth.

It would have been obvious to one of ordinary skill in the art to have combined the teachings of Keller and Hill with Aberg et al and add a NSAID to the toothpaste or dental floss for the treatment of periodontal disease because Aberg teaches periodontal disease relates to a condition in which the gingival and the alveolar bone become detached if periodontal disease is not treated, and the bacteria that causes the periodontal disease can gain access to the blood stream and cause vascular disease. Therefore, one of ordinary skill in the art would have been motivated to add Aberg's NSAID to toothpaste for brushing or add NSAID to dental floss for flossing to remove biofilm in pockets of the tooth of the patient suffering from periodontal disease because Keller teaches that therapeutic agents may be added to such formulation with a reasonable expectation of success.

Also because Keller teaches that self-treatment may be carried out twice every 24 hours or between 8-12 hours, based on the severity of the gingival treatment, the frequency of brushing twice every twenty four hours meets the limitation of "at least once every twenty four hours". It is well known in the art to floss or brush your teeth

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after meals, thus a patient with a gingival detachment would be inclined to brush or floss his/her teeth after every meal to prevent food particles entering the gingival pocket in order to minimize decay that may prolong treatment.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. V. G./
Examiner, Art Unit 1618
4/30/10

/Robert C. Hayes/
Primary Examiner, Art Unit 1649